

# **EXHIBIT B**

**AUGUSTINE**  
BIOMEDICAL+ DESIGN

Mr. Gary Maharaj  
CEO  
Arizant Healthcare Inc.  
10393 West 70<sup>th</sup> St.  
Eden Prairie, MN 55344

April 2, 2010

Re: Arizant's obligation to disclose and report

Dear Gary,

Two-and-a-half years ago we disclosed to Arizant and to the world that the internal airflow paths of Bair Hugger blowers are contaminated with bacteria and cannot be decontaminated (see [BlowingAirIsRisky.com](http://BlowingAirIsRisky.com)). The presence of bacteria in the airflow path and in the outlet air of the Bair Hugger blower presents an obvious risk of contamination in the operating room. Since then we have completed three more studies (one published and two pending publication), that all show the contamination issue to be much worse than we originally reported. The additional facts that; 1.) the airflow path cannot be cleaned (much less "decontaminated") and 2.) that decontamination instructions have not been supplied by the manufacturer, directly violate the Medical Devices Directive (MDD) for CE certification, FDA and Health Canada regulations.

Six months ago, we disclosed to Arizant and to the world that the waste heat from Bair Hugger warming disrupts the protection of laminar flow ventilation in the operating room. In subsequent research pending publication, we have shown that, in the presence of laminar flow and a single "surgeon" standing by the operating table, waste heat from a Bair Hugger lower body blanket can mobilize contaminants from the floor and convey them to the surgical site in such high concentrations that 50% of the air at the surgical site is from the floor and 50% is from the laminar flow ventilation.

I have enclosed a partial list of current research regarding the contamination problems from FAW. Doing this research has not been easy since whenever Arizant finds a study that is about to start, they have swooped into that hospital and exchanged all of the old blowers for new ones, for free! If my equipment was found to have a major problem, especially if it involved patient safety, I would want to characterize and fix that problem ASAP – before the plaintiff's attorneys got a hold of it. Just the opposite seems to be occurring here. Either Arizant is actively trying to prevent research that could help document and define the problem or you have an unannounced free upgrade program and an amazing timing coincidence with our research projects.

At this point, there is no question that FAW creates an increased risk of wound contamination during surgery. As such, you have a reporting obligation to both the regulatory authorities and to your customers. Instead, Arizant has taken the erroneous position that until infections are proven to have been caused by FAW, there is no problem that needs reporting. This is a similar logic to Guidant failing to fix their faulty

defibrillator leads (which they knew were faulty), because no one had been proven to have been killed by the failures. As you know, Guidant was not only forced into a mandatory recall that nearly destroyed the company, but is now under criminal indictment.

Inexplicably to me, Arizant has chosen to publicly deny, mislead and even lie to customers about the problems. You are obfuscating the contamination issue in the rhetoric of “no proven infections” and quoting from woefully inadequate infection studies, when the issue (at this date, at least) is contamination and not infection. You are treating the contamination issue as though it were an inconvenient marketing attack rather than a patient risk that requires reporting. This is a regulatory issue, not simply a marketing inconvenience.

Even more inexplicably, you have recently made the situation even worse. In the face of demands by researchers that you add a hose-end filter because of blower contamination, you have recently reduced the effectiveness of your already-inadequate inlet filtration. While continuing to claim “high-efficiency .2 micron” filtration to the US FDA, the UK National Health Service and your customers, you have actually reduced the efficiency of your inlet filter to only 61.3%. Since “High Efficiency” aka “HEPA” is defined as 99.97% efficient, your current filter is nowhere near “high efficiency” and in fact is not too much better than a window screen. At the very least, this reduction in safety required a full ISO 14971 Risk Analysis and submission of a new 510(k). I can only assume that this change was made to improve the bottom-line for your financial owners, or to provide the air-flow needed for your expensive new underbody blankets. In any case, making the change secretly was wrong. I urge you to report and fix the problem.

Since the internal airflow path of a Bair Hugger blower cannot be cleaned, much less decontaminated, it is arguable that your problem cannot be fixed – the regulations clearly call for decontamination of reusable devices. However, it is possible that the regulators would regard adding a hose-end filter as a reasonable substitute for decontamination. I suggest that this positive outcome is most likely if you voluntarily bring the problem and the solution to the regulators yourselves.

As I am sure you know, we have patents pending on every practical method of adding a hose-end filter to a convective warming system (see enclosed). Please let me know if you have an interest in acquiring them. Personally, I believe that the short-term survival of Bair Hugger, is dependent on adding a hose-end filter. You may, of course, choose to ignore our intellectual property and create your own hose-end filter. This would lead to litigation when our patents issue.

No matter what you decide in this regard, when our currently submitted research studies are accepted for publication (which we anticipate by mid-May), we will take this evidence of contamination to the regulators in the US and Europe (FDA, Health Canada and 27 Competent Authorities in the EU countries). As we see it, there are 29 separate opportunities for us to educate a regulatory authority about the contamination risks created by Bair Hugger.

Consider that it only takes one airborne bacterium to infect an orthopedic implant, and we can show that in the presence of Bair Hugger warming, 50% of the air above the surgical site came from the contaminated blower and floor air. Also consider that it only takes one of the 29 regulators, who comprehends the seriousness of this risk and presumably the rest will follow that lead. If necessary, however, we will support even more research—including DNA matching of the bacterium cultured from a wound infection against the bacteria found inside the Bair Hugger blower used on that infected patient.

Unless I am missing something, full and immediate reporting, restoring inlet filter efficiency to HEPA standards and adding a HEPA hose-end filter, is Bair Hugger's only chance to survive a mandatory recall. Of course, we cannot assure you that the regulators will agree - the regulations do specify "decontamination" with no mention of filtration as an acceptable alternative. However, the chances of the regulators agreeing seem to be much higher if you preemptively bring your own problem to them with a solution in hand.

I have no doubt that HotDog conductive fabric warming will ultimately replace FAW. The question for you to answer is the following; is Bair Hugger going to be replaced quickly and catastrophically by a mandatory recall, or do you survive a voluntary recall and live to fight another day? Obviously, avoiding a mandatory recall is critical to maintaining shareholder value.

I am available to discuss this offer in more detail by phone or in person.

Regards,



Scott Augustine MD  
CEO

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Mr. Gary Maharaj  
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April 19, 2010

Dear Gary,

We listened to Mr. Olmsted's presentation on behalf of Arizant to the ASA Committee advising Medicare, with interest. While there were many points that could be debated, I am compelled to dispute the CFD study that was referenced.

CFD is commonly used to predict or to explain reality. I have never heard of computer modeling being used to refute or deny reality! Obviously CFD is only as good as the model, the assumptions and the inputs to the model. However, when the CFD outputs conflict with reality, reality wins every time. In this case, the reality is clear, and therefore you need to assume that you have a CFD problem. You certainly should not present to Medicare, data that you know to be incorrect.

For Olmsted to say that (paraphrased) "FAW has no effect on laminar flow ventilation," is outrageous. Basically he is saying that hot air, even 1000 watts of it, does not rise! This statement is clearly inconsistent with basic physics. More important, his conclusion is not consistent with experimental reality. It's also inconsistent with other CFD studies.

Every CFD study that I'm aware of that has looked at the effect of waste heat in laminar flow ventilation has come to the same conclusion: heat sources (human bodies, lights etc) mess up laminar flow. Since FAW produces at least ten times more waste heat than the other heat generators that have been studied, how can your expert possibly conclude that it has no effect? I see only three possible explanations for this absurd conclusion:

- 1.) Your CFD "expert" is incompetent.
- 2.) Your CFD model is inadequate and does not account for the effects of heat.
- 3.) The inputs that Arizant presumably supplied to your expert were erroneous, for example:
  - a.) The Bair Hugger heat was not turned on – trying to confuse waste air with waste heat, like you did in your recent UK advertisement.
  - b.) The heat was not put under the surgical drape – you did not use a lower body or under body blanket.
  - c.) You did not put a surgeon next to the OR table.

Since your CFD expert works at the NIH, I have to assume that #1&#2 are not the problem. That leaves #3. It seems most likely to me that Arizant gave the CFD expert faulty inputs. That seems a bit dishonest. Obviously, if you're using CFD data to try to

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refute our video/experiment, you have to set up the same conditions as in the experiment (BH heat on high, lower body blanket under a surgical drape and a surgeon by the table). I don't think you guys did that.

Having your paid agent Mr. Olmsted "testify" to an Advisory Committee to Medicare on behalf of Arizant with information that you know to be false, seems a bit risky for a company still in the shadow of a CIA. You need to quickly set the record straight with Dr Hannenberg and the ASA Committee. Please correct this false testimony in writing and copy me with the correction in the next week. If I don't have a copy of your correction by April 27, I will correct the matter with the ASA Committee for you. Misleading Medicare with false data is clearly unacceptable, and I will not let you do that.

Regards,



Scott Augustine MD

Cc: Mr. David Westlen  
Mr. Russell Olmsted

Gary — Do you get the feeling that things are quickly spiraling out of control? Olmsted's presentation and your defensive ~~and~~ in the UK give the impression that you guys are panicking!

I do believe that failing to fix your two critical problems will not only sink Arizant but will also expose the management team and Board to personal risk and liability. You have two critical problems to deal with but the good news is that if you don't panic, they are both solvable. I'm offering to sell you the solution to the contamination problem and there are several possible solutions to the lumbar flow disruption problem.

With or without our help in solving these problems, you are on a really short timetable. I guarantee you that we will be taking the contamination issue to the regulators before June and that action will instantly limit your options. Maybe we should get together and talk about these matters. Scott